Participant Experience with Continuous Glucose Monitoring: Acceptability and Implications for Physical Activity Behavior Modification

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Honors Thesis
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University of North Carolina
2020

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ABSTRACT

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Background. Continuous glucose monitoring for the management of type I diabetes (T1D) has become increasingly widespread; however, few studies have investigated this device's potential as a tool for those with prediabetes or type II diabetes (T2D).

Objective. The objective of this study was to assess the acceptability of continuous glucose monitoring (CGM), the relationship between CGM acceptance and frequency of scanning, and the association of scanning frequency with physical activity (PA) behaviors among those with prediabetes and T2D enrolled in a weight loss program.

Methods. The parent T2Connect trial was a single-arm, non-blinded 12-week study designed to include twenty participants with prediabetes or non-insulin dependent T2D. The Technology Acceptance Model (TAM-CGM) was administered at baseline to assess perceptions of CGM acceptability. All participants were instructed to weigh themselves daily, record dietary intake with the Traffic Light Diet approach, track their physical activity (PA) with a wearable PA tracker, and engage in weekly coaching sessions throughout the study. Participants were also randomized to wear a CGM for 14-days or the full 12-weeks. The study outlined in this paper analyzes data from the first two weeks of the described T2Connect parent trial, such that all participants ($n = 11$) received the same baseline measures and utilized their digital tools for the same amount of time. Linear regression and ANOVA analyses were used to evaluate the associations between CGM acceptability, scanning frequency, and physical activity variables.

Results. On average, participants reported more benefits to CGM use than barriers at baseline. The overall benefits to barriers ratio (BBR) was 1.22, and persons with a BBR greater than 1 performed an average of 3.09 additional scans per day compared to persons with a BBR less than or equal to 1 ($p = 0.1872$). Over the first two weeks, we found that the association between average scanning frequency and average glucose was negative, with a beta coefficient of 1.15 ($p = 0.2424$). The association between average scans per day and total steps per day was positive (estimate = 545.20, $p = 0.0006$) while the association between total steps per day and average glucose was negative (estimate = -0.000195, $p = 0.7990$). Between weeks 1 and 2 of the program, participants scanned 0.65 times more, increased their steps by 1038, and decreased their average glucose by 6.63 mg/dL (p = 0.16, 0.02, and 0.03 respectively).

Conclusion. Preliminary results suggest that baseline perceptions of CGM technology influence frequency of scanning, which is in turn associated with behaviors like physical activity that can lead to improved diabetes management. Future research is warranted to explore the potential mediational role of physical activity in the relationship between scanning frequency and glucose control.

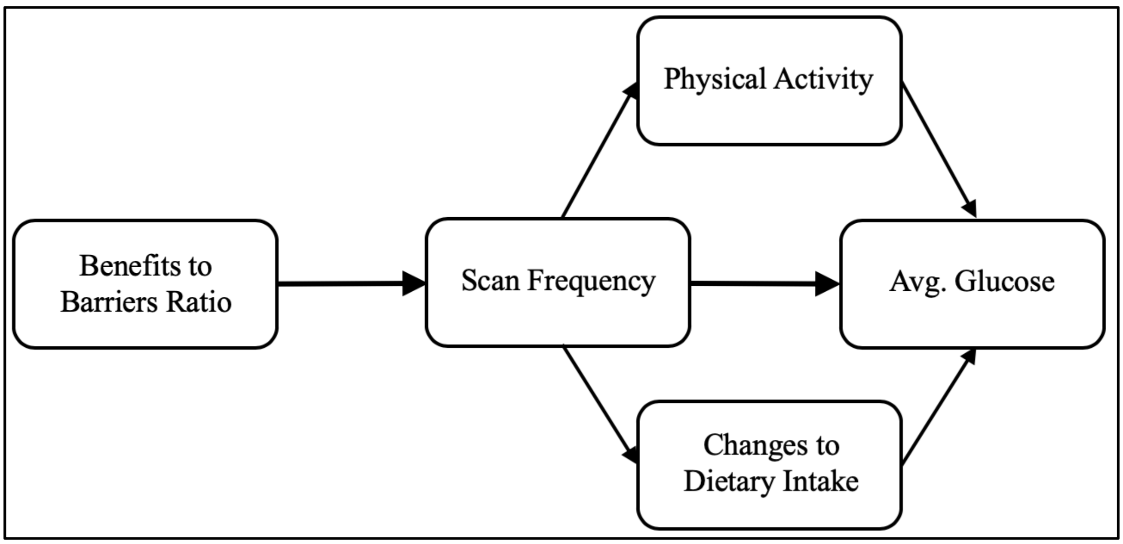
INTRODUCTION

Despite medical advancements and prevention efforts, diabetes mellitus has persisted as a leading cause of adverse health outcomes, morbidity, and mortality.[1] The CDC reports that more than 1 in 3 American adults are already considered prediabetic, and recent projections predict that the prevalence of type 1 and type 2 diabetes will increase by over 50% between 2015 and 2030.[2,3] These estimates seem bleak; however, there is evidence to suggest that their trajectories may be altered through lifestyle interventions. Results from the Diabetes Prevention Program (DPP) have shown that behaviors such as managing dietary habits, increasing physical activity (PA) levels, and maintaining a healthy weight can produce significant reductions in the progression of diabetes and its related complications.[4,5] More specifically, prediabetic individuals that engaged in these lifestyle interventions decreased their risk of developing T2D by 58%.[5] To encourage continued adherence to these behavioral modifications and thereby prompt favorable health outcomes, reliance on modern technology may prove especially useful.

In the ongoing effort to improve health and well-being, wearable devices have emerged as promising assets to behavioral monitoring and modification.[6,7] These technologies allow their users to gain instant access to personalized health data, as well as the power to easily track subtle trends that are often overlooked. As of 2019, the Pew Research Center reports that one in every five U.S. adults currently wears some type wearable health tracker.[8] One particularly appealing wearable is the continuous glucose monitor (CGM). These devices require a small sensor to be inserted beneath the skin and worn for 10-14 days. The sensor measures the concentration of glucose in the body's interstitial fluid, and transmits the data to a receiver that displays the information as a graph with overall blood glucose level (BGL) trends, BGL directional predictions, and updates as new readings are processed.[9] Where traditional self-monitoring blood glucose (SMBG) methods captured a static picture of BGL concentration, CGM systems create a more holistic and dynamic picture of BGLs at any given moment. Accordingly, this technology ought to play a bigger role for all persons experiencing abnormal glucose patterns rather than just the type 1 diabetes (T1D) population that extant literature currently suggests.

The focus on CGM technology for T1Ds is explained by their daily experiences with rapid BGL changes and the need to prevent hypoglycemic episodes, which are not as commonly experienced by their prediabetic and T2D counterparts.[10] Even so, the CGM likely plays an important role for T2D populations by encouraging behavior modifications that result in decreased hyperglycemic events and overall improved diabetes management. In the few studies that have investigated the efficacy of CGM technology as a tool for T2Ds, the results are promising. Vigersky et. al. reported that T2Ds using CGMs experienced a 1.0%, 1.2%, and 1.3% decrease in HbA1c levels after 12 weeks, 24 weeks, and 52 weeks respectively.[11] Similarly, another study by Yoo et. al. showed that the continuous stream of BGL information from CGM technology helped users to understand the influence of physical activity, diet, and other modifiable behaviors on BGL trends.[12] These findings suggest that the relationship between continuous glucose monitoring and modifiable behaviors can be targeted to improve overall diabetes management. More specifically, proponents of CGM technology reason that the continuous stream of glycemic data will prompt greater attention to, and modification of, behaviors that will help keep BGLs within target range.[13] If patients can make the connection between their lifestyle choices and the immediate physiological consequences that follow, continuous glucose monitoring may prove to be an essential tool for pre- and type 2 diabetes management. As a result, we aimed to: 1) assess the acceptability of CGM technology among persons with prediabetes and T2D; 2) determine the relationship between CGM acceptability and daily sensor scanning frequency; 3) investigate the role that PA plays in the relationship between scans per day and average glucose; and 4) examine changes in scans per day, total steps per day, and average glucose between weeks 1 and 2 of the study program. **Figure 1** below depicts the potential role that these behaviors of CGM scanning, dietary monitoring, and physical activity play in overall glucose regulation.

Figure 1. Overall schematic of study aims and hypothesized relationships between CGM acceptability, scanning frequency, physical activity, dietary habits, and average glucose.



SPECIFIC AIMS

Aim 1. To determine the relationship between perceived benefits & barriers of CGM use and the frequency of daily sensor scanning among those with prediabetes and type II diabetes.

Hypothesis. Persons with a benefits to barriers ratio (BBR) greater than 1 at baseline will scan more times per day compared to those with a BBR less than or equal to 1.

Aim 2. To determine the association between the frequency of daily sensor scanning and glucose control over 14 days.

Hypothesis. Increased frequency of scanning will be negatively associated with average glucose.

Aim 3. To examine the role of physical activity (PA) in the relationship between scanning frequency and glucose control.

Hypothesis 3a. Scanning frequency will be positively associated with the PA behavior of total steps per day.

Hypothesis 3b. Total steps per day will be negatively associated with average glucose readings.

Hypothesis 3c. Scanning frequency can lead to improved diabetes management through its positive association with total steps per day.

Aim 4. To examine the changes in scanning frequency, steps, and average glucose per day from week 1 to week 2 of the program.

Hypothesis. On average, there will be favorable changes in these three variables (i.e. scans increase, steps increase, average glucose decreases) from week 1 to week 2 of the program.

METHODS

Study Design. The T2Connect parent trial was a single-arm, non-blinded pilot study designed to use CGM technology to promote weight loss and improve diabetes management among those with prediabetes and non-insulin dependent T2D. The study utilized digital tools and weekly, in-person coaching sessions over a 12-week timeframe. Participants were first screened for eligibility before completing baseline questionnaires and having their height, weight, and HbA1c measured. Each participant attended an official kick-off session where he or she was introduced to the Traffic Light Diet to use for dietary tracking and provided a scale, physical activity tracker (Fitbit Inspire), and CGM (Abbott Freestyle Libre) to practice daily self-weighing (DSW), PA tracking, and BGL monitoring, respectively. Participants were also given access to the T2Connect mobile app that displayed personalized weight trends, daily PA and dietary goal progress, behavioral lesson plans, additional resources, and overall summary statistics for the week. At the end of the kick-off session, participants were assigned to either 14-day or full 12 weeks of CGM wear using randomly generated numbers. Regardless of how long they were assigned to wear the CGM, all participants met with a study coach each week for the full 12 weeks to review individual progress, troubleshoot, and set goals for the coming week.

The current study focuses on responses to the Technology Acceptance Model-CGM (TAM-CGM) in order to investigate CGM acceptability at baseline. CGM and PA data from the first two weeks of the program were also analyzed. These data were downloaded and examined from their respective databases (i.e. RedCap, LibreView, and Fitbit portals) for analysis. Analyses of early intervention findings examined the efficacy of participants' first in-person coaching session between the first and second weeks of the program.

Sample and Eligibility Criteria. The current study consisted of 11 individuals with prediabetes or non-insulin treated T2D. All participants provided informed consent prior to participation in the study. Participants were eligible to participate if they met the following criteria: 1) age 20 – 65; 2) diagnosed with T2D or pre-diabetes and not taking medication used to treat diabetes; 3) were experiencing poor glycemic control (HbA1c > 5.7%); 4) were overweight with a Body Mass Index (BMI) of 25-40 kg/m^2; 5) could speak and write English; 6) were not meeting the American College of Sports Medicine recommendation of 150 minutes of Moderate to Vigorous Physical Activity each week;[14] 7) had an iPhone with a data and text messaging plan; 8) had home wi-fi access; 9) were able to attend weekly visits at the UNC Weight Research Program clinic; and 10) could reasonably obtain written approval from their primary care provider for participation in the study.

Outcome measures. *CGM acceptability* was assessed through the Technology Acceptance Model, expanded to include CGM-specific factors (TAM-CGM). The TAM is a well-established model used for testing the acceptance and usage of technologies, and may be adapted to assess specific technological devices.[15] It consists of a 25-item questionnaire that asks participants about their perceptions of CGM use and overall technology-related self-efficacy. Two subscales were analyzed in this study's questionnaire, and these items were rated on a 6-point Likert scale ranging from *strongly disagree* (1) to *strongly agree* (6). The subscales were split into two overall categories, Perceived Benefits of CGM Technology and Perceived Barriers of CGM Technology (**Table 1**), so that an overall benefits to barriers ratio (BBR) could be calculated for each participant. *Average Glucose and Daily Sensor Scan Frequency* data were both captured by the CGM (Abbott Freestyle Libre) and accessed from its associated LibreView digital platform. *Physical activity* data, measured as total steps per day, was collected using a physical activity tracker (Fitbit Inspire, San Francisco, CA).

Table 1. Subscales for the TAM-CGM Questionnaire

Perceived Benefits of CGM Technology	**Perceived Barriers to CGM Technology**
Perceived Reliability (4 items) Usefulness (3 items) Ease of Use (3 items)	Information Overload (4 items) Technology-Related Self-Efficacy (3 items) Visibility of Body Change (4 items)

Statistical Analyses. The analyses in this study were conducted using SPSS. The first aim was to determine the relationship between perceived CGM benefits & barriers reported at baseline and the frequency of daily sensor scanning over the first two weeks of the study. First, a benefits to barriers ratio (BBR) was created to represent CGM acceptability as a single variable. The BBR was calculated by dividing the sum of the TAM-CGM benefits items by the sum of the barriers items for each participant. A linear regression model was then used to determine the association between the BBR and average daily scans per person.

The second and third aims examined the associations between the frequency of daily sensor scanning, physical activity, and glucose control. Accordingly, analysis of variance (ANOVA) tests were used to model the associations between: 1) scans per day and average daily glucose; 2) scans per day and steps per day; and 3) steps per day and average daily glucose for each participant and for the overall sample. The models were also used to examine between-person differences for these associations.

For the fourth and final aim, paired sample t-tests were conducted to examine the changes in scanning frequency, steps, and average glucose per day from week 1 to week 2 of the program. For all of the statistical analyses conducted in this study, p-values less than or equal to 0.05 were considered statistically significant.

RESULTS

Participant Characteristics. Participants were on average 57.3±5.3 years of age, weighed 91.5±16.1 kg, and had an average BMI of 33.2±4.0 kg/m^2 and HbA1c of 6.9±1.4%. The sample was largely composed of female participants (81.8%). Prior to enrollment, only three out of the 11 participants (27.3%) had previous experience using a glucose monitor to check their BGL (**Table 2**).

Table 2. Sample characteristics (n=11)

Variable	Value
Female, n (%)	9 (81.8)
Age (years), mean (SD)	57.3 (5.3)
Weight (kg), mean (SD)	91.4 (16.1)
Height (cm), mean (SD)	166.7 (8.6)
BMI (kg/m^2), mean (SD)	33.2 (4.0)
HbA1c (%), mean (SD)	6.9 (1.4)
Previous experience monitoring BGLs, n (%)	3 (27.3)
Education, n (%)	
Less than college degree	1 (9.1)
≥ College degree	10 (90.9)
Employment status, n (%)	
Employed full-time	9 (81.8)
Employed part-time	1 (9.1)
Other	1 (9.1)
Household income, n (%)	
Below $50,000	1 (9.1)
≥ $50,000	10 (90.9)

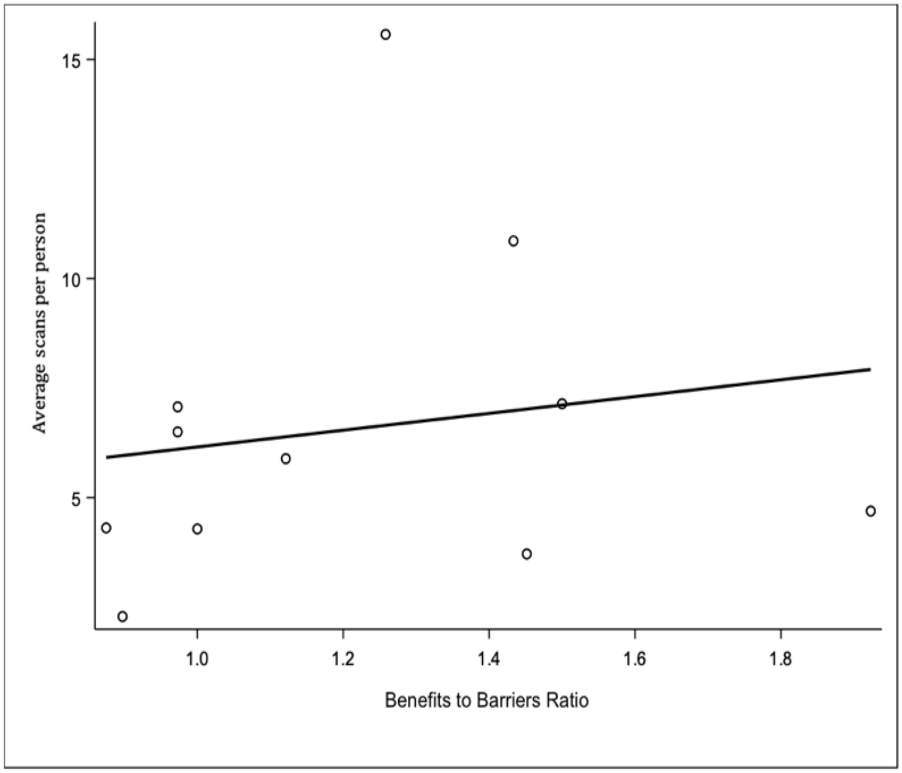
Preliminary Findings. Over the first two weeks of the T2Connect study, participants averaged 6.28 scans, 6,583 steps, and a BGL of 113.8 mg/dL per day (**Table 3**). All participants complied with study protocols by wearing their physical activity trackers and CGM sensors each day for these first two weeks.

Table 3. Average scans, steps, and glucose data per day for each participant (n = 11)

	Average Over 14 Days		
	Scans	**Steps**	**Glucose**
ID 3	10.9	5356.6	103.21
ID 30	5.9	5933.4	137.8
ID 32	4.3	6214.2	92.8
ID 43	4.7	4597.4	263.7
ID 74	6.5	3817.4	97.9
ID 81	7.1	10213.1	93.4
ID 85	4.3	7956.4	114.7
ID 88	3.7	4308.4	144.0
ID 90	7.1	10688.5	156.5
ID 89	15.6	5536.4	121.1
ID 94	2.3	12101.1	91.6
Overall Average	6.3	6583.1	113.8

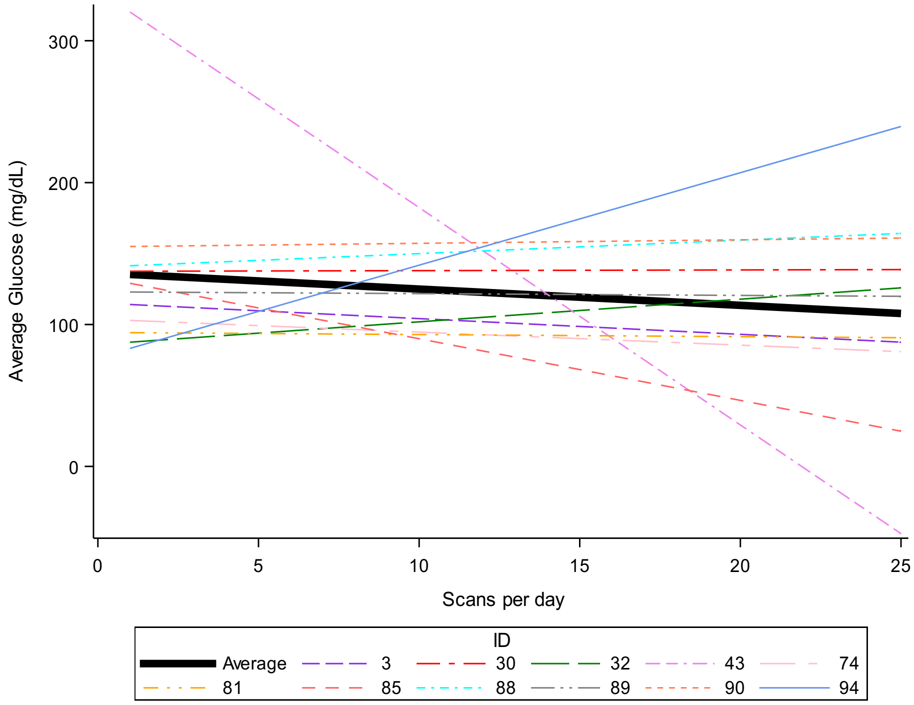
Benefits to Barriers. The overall mean benefits to barriers ratio (BBR) for this sample was 1.22. The association between the BBR and average scans per person was positive, with a beta coefficient of 1.92, though not statistically significant ($p = 0.6226$) (**Figure 2**). A second regression model found that those with a BBR greater than 1 performed an average of 3.09 additional scans per day compared to persons with a BBR less than or equal to 1.

Figure 2. Regression model for the association between the BBR and average scans per person



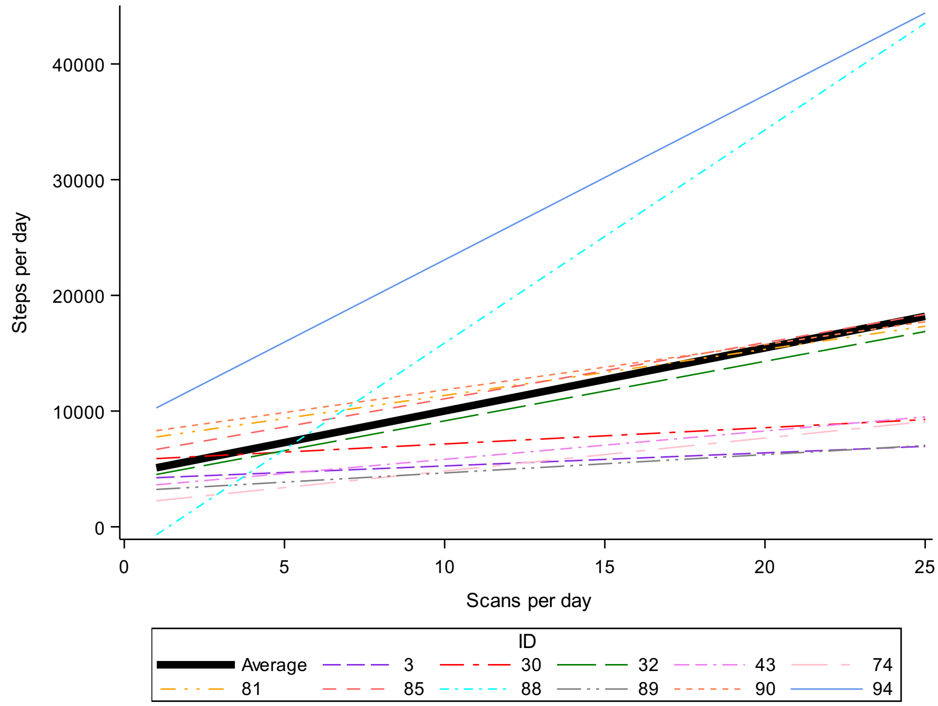
Scans and Average Glucose. The association between participant scanning frequency and average glucose per day was negative but not statistically significant (estimate = -1.15, p = 0.2424). Accordingly, each additional scan per day was associated with an average 1.15 reduction in average daily glucose levels. Testing the null hypothesis of no between-person variation in the association between scans per day and average glucose, it was found that the variation in this association was statistically significant (F = 3.11, p = 0.0014), suggesting that there is a significant between-person difference in the association between scans per day and average glucose. In other words, the association between scans per day and average glucose varies from person to person. This between-person variation finding can be seen graphically by looking at the slopes of each participant's regression line, and noting how both their directions and magnitudes vary from person to person (**Figure 3**).

Figure 3. Individual and average associations between scans per day and average glucose



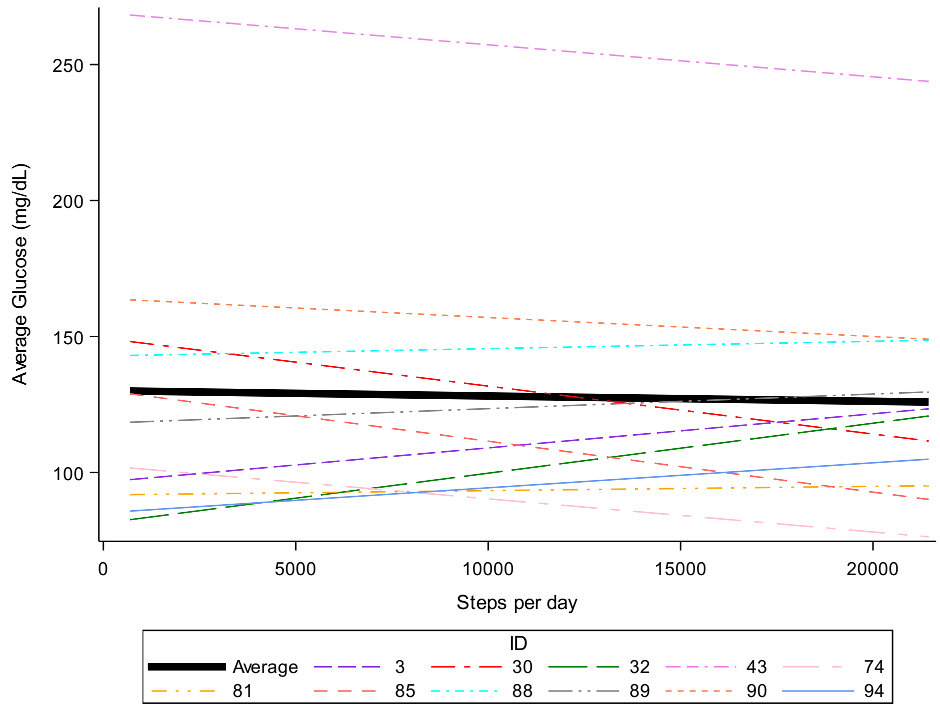
Scans and Steps. The association between scans per day and steps per day was positive and statistically significant (estimate = 545.20, $p = 0.0006$). Under this ANOVA model, each additional scan was associated with an increase of 545 steps per day on average. The model was also used to test the null hypothesis of no between-person variation in the association between scans per day and steps per day. The variation in this association was not statistically significant ($F = 0.93$, $p = 0.5084$). In other words, the association between scans per day and steps per day does not vary significantly from person to person (**Figure 4**).

Figure 4. Individual and average associations between scans per day and steps per day



Steps and Average Glucose. The association between steps per day and average glucose trended in an overall negative direction but was not statistically significant (estimate = -0.000195, p = 0.7990). This model suggests that an extra 5,000 steps per day was associated with a nearly 1 mg/dL decrease in average glucose. The model was also used to test the null hypothesis of no between-person variation in the association between steps per day and average glucose. The variation in this association was not statistically significant (F = 0.21, p = 0.9954). In other words, the association between steps per day and average glucose does not vary significantly from person to person (e.g., if persons A and B both increase their steps per day from 5000 to 10,000, both experience drops in average glucose levels drop by approximately 1 mg/dL) (**Figure 5**).

Figure 5. Individual and average associations between steps per day and average glucose



Early Intervention Findings. On average, participants performed an additional 0.65 sensor scans ($p = 0.16$), increased their steps by 1038 ($p = 0.02$), and decreased their average glucose by 6.63 mg/dL ($p = 0.03$) from week 1 to week 2 of the program (**Table 4**).

Table 4. Changes in scanning frequency, steps, and average glucose per day from week 1 to week 2 of the T2Connect program

Dependent	*Parameter*	*Estimate*	*Standard Error*	*t Value*	*Pr > |t|*
scans	Week 1 mean	6.23			
	Week 2 mean	6.88			
	Week 1 vs. week 2	0.65	0.46	1.41	0.1597
steps	Week 1 mean	6513.18			
	Week 2 mean	7551.16			
	Week 1 vs. week 2	1037.97	457.22	2.27	0.0248
glucose	Week 1 mean	132.26			
	Week 2 mean	125.62			
	Week 1 vs. week 2	-6.63	3.01	-2.21	0.0291

DISCUSSION

Unlike standard weight loss and diabetes management programs, the T2Connect trial combines digital, mobile-based tools with CGM technology and in-person coaching sessions to motivate behavioral changes in those with prediabetes and T2D. Extant literature addressing the use of CGM technology in these populations is noticeably absent. As a result, this is one of few studies to examine the potential of CGM technology to influence modifiable behaviors for weight loss and improved diabetes management among persons with prediabetes or T2D.

Because it is not standard to recommend a self-monitoring blood glucose (SMBG) regimen to those with prediabetes or T2D, it is unlikely that they are familiar with CGM technology. Even so, this study found that the majority of participants regarded the CGM with high acceptability. Participants reported greater CGM benefits than barriers on average, with an overall BBR of 1.22 for the group at baseline. A BBR greater than one, as seen in this sample, has important implications for favorable behavioral modification; more specifically, we found that those with a BBR greater than 1 scanned their CGM sensors 3.09 times more than those with a BBR less than or equal to 1. These findings suggest that CGM acceptability influences participant reliance on the device, and are clinically relevant, as they suggest that providers can motivate increased scanning behaviors by targeting patient perceptions of CGM technology.

We also examined the association between sensor scanning frequency and average glucose; findings suggested a negative association (estimate = -1.15, $p = 0.2424$). On average, each additional scan per day was associated with a 1.15 reduction in average glucose. Under this model, individuals that scanned an extra 5 times per day would reduce their average glucose by nearly 6 mg/dL. The mere act of scanning, however, is not likely to lead directly to a drop in glucose. Instead, the rationale is that individuals that scan more frequently will take that information and engage in some appropriate behavior (e.g. increase dietary monitoring, increase PA) that then lowers their BGL. In other words, it is likely that the effects of scanning frequency on glucose control operate by influencing modifiable behaviors such as physical activity, which in turn reduces glucose.[16,17]

In this study, we chose to look at how physical activity, in the form of steps per day, plays a role in the relationship between scanning frequency and glucose control. We found that 1) the association between scans per day and steps per day was positive, so that each additional scan was associated with an average increase of 545 steps per day (estimate = 545.20, p = 0.0006) and that 2) the association between steps per day and average glucose was negative, so that an extra 5,000 steps per day was associated with a nearly 1 mg/dL decrease in average glucose (estimate = -0.000195, p = 0.7990). Though the association between steps per day and average glucose was only slightly negative and not statistically significant, the overall trend points in the hypothesized direction. Putting these findings together, it is reasonable to hypothesize that PA acts as a mediator in the relationship between scanning frequency and glucose control; however, further research is needed to explore formal mediational analyses and confirm the exploratory results of this study.

Lastly, we saw that participants increased their daily scanning frequency, increased their steps, and decreased their average glucose from week 1 to week 2 of the program. Between those two weeks, participants met with their study coach to review their progress, troubleshoot any issues, and set goals for the coming weeks. The changes observed in the data suggest that the coaching session may have helped individuals to better understand how their behaviors (e.g. DSW, diet tracking, PA bouts) influence their BGLs, and the importance of frequent scanning to monitor those changes. Although this study only examined the first two weeks of the T2Connect program when all participants wore the CGM, early successes in the first weeks of behavioral interventions have been shown to be predictive of success over a longer period of time.[19,20] Recognition and improvement in these program settings can help people persist with their long-term goals, and ultimately sets them up nicely for all their future weight, diet, PA, and diabetes-related successes.

LIMITATIONS

Although the data from this study were in the hypothesized direction, there are a number of limitations worth mentioning. The small study sample and lack of demographic diversity limit the generalizability of our study findings. Only baseline measures and data from the first two weeks of the parent trial were analyzed, which makes it difficult to predict the true long-term effects of our results. Once follow-up data are collected, analyses ought to be repeated to add depth to this study's findings. Further research that conducts formal mediational analyses is also warranted before definitive conclusions can be made about any mediational role that PA may play in the relationship between scanning frequency and glucose control. Finally, this study did not examine additional behaviors besides PA (e.g. changes to dietary intake) that may influence the relationship between scanning frequency and glucose control. Future research will need to explore these alternative pathways as they were not the focus of this study.

CONCLUSION

Despite the aforementioned limitations, we were able to demonstrate CGM acceptability among those with prediabetes and T2D, the negative association between sensor scanning frequency and glucose control, and the suggestive role of that PA plays in the relationship between scanning frequency and glucose control. Furthermore, we found that in-person coaching sessions likely motivated changes in behavior from week 1 to week 2 of the study. These findings imply that behavior modification is possible by targeting baseline perceptions and understanding of program tools, including the CGM. Our study suggests that CGM technology may be an effective wearable device not only for those with type I diabetes as previously thought, but also for persons with prediabetes and T2D. As such, the aims of this study are deserving of future research to ultimately confirm our preliminary results.

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APPENDIX

Table I. The perceived benefits of CGM technology subscale items and measured averages

Perceived Benefit Items	**M (SD)**
Perceived Reliability	
1: The device is very susceptible to interferences	4.09 (0.94)
2: CGM shows too many measurement errors	4.18 (0.60)
3: Overall, I think the system is reliable	4.55 (0.82)
4: The device triggers false alarms too often	4.18 (0.87)
Usefulness	
12: CGM makes it easier to keep blood glucose levels under control	4.55 (1.04)
13: CGM improves diabetes self-management	4.91 (0.70)
14: CGM improves diabetes weight management	4.73 (0.65)
Ease of Use	
15: I think the system is easy to use	4.73 (0.65)
16: I think it is difficult to adjust the system's settings properly	4.00 (1.10)
17: Using the CGM is awkward	4.46 (0.82)

Table II. The perceived barriers of CGM technology subscale items and measured averages

Perceived Barrier Items	**M (SD)**
Information Overload	
5: Sometimes I do not know what to do with all the information provided by the CGM	2.73 (0.90)
6: CGM provides too many readings	2.64 (0.92)
7: It would be better if the CGM would provide less information	2.64 (0.92)
8: CGM delivers too much information for me	2.64 (0.92)
Technology Related Self-Efficacy	
9: Generally, I think it is easy to learn how to use a new technology	4.91 (0.83)
10: I feel very confident in my abilities to make use of new technologies	5.09 (0.83)
11: When I use a technological device, I do feel that I am in control	4.55 (1.29)
Visibility of Body Change	
18: CGM changes my body in a negative way	2.09 (0.54)
19: CGM embarrasses me because I perceive myself as being different from the others	2.09 (0.54)
20: I do not like to wear CGM because it arouses attention of other people	2.18 (0.75)
21: The CGM embarrasses me, because I have to justify myself constantly	2.09 (0.83)